

Amendments to the Claims

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims

1. (Original) Substantially pure desloratadine having an HPLC purity greater than 99.5%, and having an absorbance less than 0.15 Au at 420 nm for a 5%w/v solution in methanol, which does not show a peak for an impurity at a relative retention time in the range from about 0.85 to about 0.99 (relative to desloratadine appearing at a retention time of 25±5 minutes) which is greater than the discard limit set at less than 0.025% of total area, when tested according to an HPLC method performed using a Hypersil BDS C₈ column (15 cm x 4.6 mm, 5 μm particle size) with the following parameters:

Mobile phase: Buffer solution having a pH of about 3, methanol and acetonitrile in a volume ratio of 8:1:1.

Injection volume : 20μl

Flow rate : 1.5 ml/minute

Run time : 75 minutes

Discard limit : Set at less than 0.025% of total area

2. (Original) Substantially pure desloratadine as claimed in claim 1, wherein (a) total impurities are not more than 0.5%; and (b) no individual impurity is greater than 0.1%.

3. (Original) Substantially pure desloratadine as claimed in claim 2, wherein the total impurities are less than 0.3%.

4. (Previously presented) Substantially pure desloratadine of claim 1, 2 or 3 prepared by a process comprising acidic hydrolysis of a compound of formula 3, where R is selected from COR₁, COOR₁, wherein R₁ is selected from branched or linear alkyl containing 1

to 6 carbon atoms, cycloalkyl, alkenyl, alkynyl, aryl, aralkyl and their substituted analogs; the acidic hydrolysis comprising

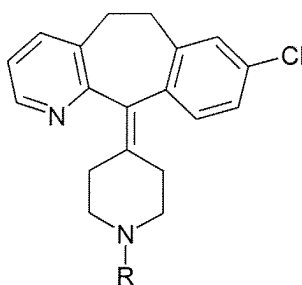
heating with a strong organic acid or a mineral acid for about 1 hour to about 24 hours,

adjusting pH of the hydrolysed reaction mixture to about 3 to 5,

optionally treating with an adsorbent,

adjusting the pH of the reaction mixture to greater than about 9, and

isolating desloratadine



Formula 3.

5. (Previously presented) The substantially pure desloratadine of claim 4 prepared by a process comprising heating to about 20° to 150°C in the presence of a strong acid.

6. (Previously presented) The substantially pure desloratadine of claim 4 prepared by a process further comprising recrystallizing desloratadine from a solvent system comprising a mixture of an alcohol and a hydrocarbon solvent.

7. (Previously presented) The substantially pure desloratadine of claim 6 wherein the alcohol is methanol and the hydrocarbon solvent is cyclohexane.

8. (Previously presented) A process for preparation of substantially pure desloratadine comprising acidic hydrolysis of a compound of formula 3, where R is selected

from COR_1 , COOR_1 , wherein R_1 is selected from branched or linear alkyl containing 1 to 6 carbon atoms, cycloalkyl, alkenyl, alkynyl, aryl, aralkyl and their substituted analogs; comprising

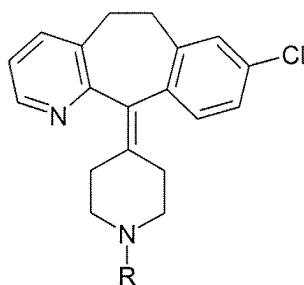
heating the compound of formula 3 in the presence of ~~with~~ a strong organic acid or a mineral acid for about 1 hour to about 24 hours,

adjusting the pH of the hydrolysed reaction mixture to about 3 to 5,

optionally treating the pH adjusted reaction mixture with an adsorbent,

adjusting the pH of the reaction mixture to greater than about 9, and

isolating desloratadine



Formula 3.

9. (Previously presented) The process as claimed in claim 8 wherein R is COOR_1 and R_1 is ethyl and the acid is methanesulfonic acid.

10. (Previously presented) The process as claimed in claim 8 wherein R is COOR_1 and R_1 is ethyl and the acid is sulphuric acid.

11. (Previously presented) The process as claimed in claim 8, comprising heating to about 20° to 150°C in the presence of a strong acid.

12. (Previously presented) The process as claimed in claim 11, comprising heating to about 60°C to 110°C in the presence of a strong acid.

13. (Previously presented) The process as claimed in claim 9, comprising heating with methanesulfonic acid for 5 to 15 hours at about 90°C to 120°C.

14. (Previously presented) The process as claimed in claim 10, comprising heating with sulphuric acid for 1 to 5 hours at about 90°C to 120°C.

15. (Previously presented) The process as claimed in claim 8, wherein adsorbent is selected from charcoal, neutral or alkaline alumina, silica and fuller's earth.

16. (Previously presented) The process as claimed in claim 8, comprising adjusting the pH of the reaction mixture to about 4 to 5, treating with charcoal, adjusting the pH of the reaction mixture to greater than about 9 and isolating desloratadine.

17. (Previously presented) The process as claimed in claim 8, further comprising recrystallizing desloratadine from a solvent system comprising of two or more solvents selected from water, alcohols, linear hydrocarbons, branched hydrocarbons, cyclic hydrocarbons, aromatic hydrocarbons, ethers, ketones, nitriles, esters, and their halo or substituted analogs and the like.

18. (Previously presented) The process as claimed in claim 8, further comprising recrystallizing desloratadine from a solvent system comprising a mixture of an alcohol and a hydrocarbon solvent.

19. (Previously presented) The process as claimed in claim 18 wherein alcohol is methanol and hydrocarbon solvent is cyclohexane.

20. (Previously presented) The process as claimed in claim 19, wherein the ratio of methanol:cyclohexane is 1:14 v/v.

21. (Previously presented) The process as claimed in claim 8 for preparation of substantially pure desloratadine as described in claim 1, 2 or 3.

22. (Canceled)